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09/697,590	10/27/2000	Judith Fitzpatrick	018792/0177	3507

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FOLEY AND LARDNER  
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EXAMINER

TURNER, SHARON L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/697,590

Applicant(s)

FITZPATRICK ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-22, 24, 26-53, 55-58 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 7-22, 24 and 26-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-5, 7-22, 24, 26-53 and 55-58 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **Response to Amendment**

1. The amendment filed 10-4-04 has been entered into the record and has been fully considered.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. As a result of Applicant's amendment, all rejections not reiterated herein have been withdrawn by the Examiner.
4. Claims 1-5, 7-22, 24, 26-53, and 55-58 are pending. Claims 6, 23, 25 and 54 are canceled and claims 55-58 are newly presented.
5. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
6. As a result of Applicants amendment, all rejections not reiterated herein have been withdrawn by the Examiner.

### **Election/Restriction**

7. Applicant's election with traverse of Group I, claims 1-10 and 23-25 and 54 in part drawn to the extent of the peptide HARL, designated as SEQ ID NO:2, residues 292-295 in Paper No. 10 is acknowledged.

The traversal is on the ground(s) that the peptides are sufficiently related to at least claims 26-53 directed to various methods of using the peptides and that a thorough search would necessarily encompass a search for the methods of use and would not constitute a serious burden. Applicants argue that the search and examination of overlapping sequences does not represent an undue burden.

This is not found persuasive because each of the inventions are patentably distinct as each delineates different sequence structure capable of different effects, functions and use. A search for one would not necessarily constitute a search for the other. Further it is noted that the election of peptide sequence as required in the restriction requirement is as an election of invention and not of species as indicated by applicant. A search of any particular sequence does not represent a search of any other and the claim structure does not evidence a proper genus. Rejoinder would only be reconsidered upon the indication of an allowable generic claim with common structure and function as required. The requirement is still deemed proper and is therefore made FINAL.

8. In the response of 1-28-04 claim 1 was amended so that it is no longer drawn to the HARL element. Thus, claims 1 and 2 are no longer directed to the elected invention.

9. Claims 1-5, 7-22, 24 and 26-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

10. In the response of 10-4-04 new claims 55-58 are presented and are drawn to the elected HARL sequence. Accordingly, claims 55-58 are under examination.

### **Rejections Necessitated by Amendment**

#### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 55-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12 of copending Application No. 10/146,130. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending application is similarly drawn to isolated neural thread protein (NTP) peptides corresponding to species of HARL sequences, with additional NTP residues and which are deemed to inherently bind to themselves based upon the presence of the NTP sequence, known and evidence to bind to itself within the art, see for example, specification and de la Monte of record below. While the '130 claims are drawn to the peptides provided in a composition of matter claim, patenting of the claim may render obvious instant peptide comprising the same segment of neural thread protein as instantly claimed. The species would anticipate the genus of peptides now recited.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

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13. Claims 55-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 55-58 are newly presented as in the amendment of 10-4-04. Support for the new recitations is as noted in the figure spanning pp. 20-23. These citations have been fully considered. However, support for the recitations is not garnered due to the inexactness of the recitations as noted. In particular, Applicant's claims recite elements with respect to an "HARL" core sequence whereas in contrast the specification only denotes longer core sequences as in for example elements a-d at p. 8-9 spanning which recite for example "THARLIL", "HHARLCL", "MFARLIL", and "HHARLIF". Also noted at p. 9 are cores of "HARLML" as directed at p. 9, line 5. While the specification at p. 9, lines 15-16 does recite "Preferably, the Harlil peptide having additional amino acid residues does not exceed 25 total amino acids in length", the cores are not of "HARL" as now recited in the claims. Moreover, the claims combine particular elements, for example the preamble of "does not exceed 25 amino acids in length" is combined with elements a) and b) of the claims directed to a core of "HARL" and "additional amino acids before and after the amino acid sequence HARL of said peptide correspond to those amino acids found in a Neural Thread Protein (NTP) sequence" and as in claims 56-58 element c) said peptide binds to NTP. Support is not garnered in particular for this combination of elements to define a new sub-genus not supported

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by the specification as originally filed. Accordingly, the full recitations of the claims constitute new matter.

### **Claim Rejections - 35 USC § 102**

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 55-58 are rejected under 35 U.S.C. 102(e) and (b) as being anticipated by Kubota et al., US 5,834,287 filed Feb. 26, 1996 and issued Nov. 10, 1998, page 1 and columns 37-42, SEQ ID NO's:5-10 as further evidenced by de la Monte, US 5,830,670, SEQ ID NO's:30, 36, 40, 48, 120 and 121.

Kubota et al., teach peptides of SEQ ID NO's:5-10. The length of the peptides are from 17-21 amino acids in length. In particular, SEQ ID NO:8 is comprised of the sequence "LDWAEASAGD**HARL**LE" comprising the HARL motif and additional amino acids before and after the amino acid sequence HARL of said peptide correspond to those amino acids found in a Neural thread protein sequence. In particular, the full length neural thread protein is noted as evidenced in de la Monte US 5,830,670 below. The amino acids "LDWAWASAGD" prior and "LE" after are additional amino acids that are found in a neural thread protein sequence. The claim does not require that the amino acids bear any particular homology to any particular portion of the neural thread protein sequence but merely require that they may be found in the full length sequence. In particular, the sequence bears 100% similarity where bolded (HARL) and accordingly is a homolog of HARL in that it comprises the HARL motif further bears additional sequences of the neural thread protein. Further, while the reference is silent as to the peptide binding NTP such is deemed an inherent characteristic as the peptide is part of NTP and NTP is known and evidenced to bind to itself. Thus, this property is deemed inherent absent convincing factual evidence to the contrary. The PTO has insufficient resources to test for the property itself. Thus, the peptide meets the limitations of claims 56 and the mimetic of claims 57 and 58. (The mimetics themselves are not limited either structurally or functionally and thus any peptide bearing any region of similarity to the peptide would meet the limitations of a mimetic.)

16. Claims 56-58 are rejected under 35 U.S.C. 102(a) as being anticipated by Rosen et al., WO 00/55199 published 21 September, 2000, page 1 and 74, SEQ ID NO:123 as



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further evidenced by de la Monte, US 5,830,670, SEQ ID NO's:30, 36, 40, 48, 120 and 121.

Rosen et al., teach peptide of SEQ ID NO:123. The length of the peptide is 17 amino acids comprised of the sequence "**ASASQSAGITGVSHHA**" bearing 65.4% identity to SEQ ID NO:2 residues 270-295 "ISGPCDLP**ASASQSAGITGVSHHARL**". In particular, the sequence bears 100% similarity where bolded and accordingly is a homolog of HARL in that it comprises the HARL motif with only the RL deleted (a homolog) and further bears additional sequences of the neural thread protein. In addition, the full length neural thread protein is noted as evidenced in de la Monte US 5,830,670 below. The amino acids prior are additional amino acids that are found in a neural thread protein sequence. In particular, the sequence bears 100% similarity where bolded and accordingly is a homolog of HARL. Further, while the reference is silent as to the peptide binding NTP such is deemed an inherent characteristic as the peptide is part of NTP and NTP is known and evidenced to bind to itself. Thus, this property is deemed inherent absent convincing factual evidence to the contrary. The PTO has insufficient resources to test for the property itself. Thus, the peptide meets the limitations of claims 56 and the mimetic of claims 57 and 58. (The mimetics themselves are not limited either structurally or functionally and thus any peptide bearing any region of similarity to the peptide would meet the limitations of a mimetic.)

17. Claims 56-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Lo et al., US 6,610,506 filed Nov. 29, 1996, page 1 and columns 121-122, SEQ IDNO:53 as

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further evidenced by de la Monte, US 5,830,670, SEQ ID NO's:30, 36, 40, 48, 120 and 121.

Lo et al., teach peptide of SEQ ID NO:53. The length of the peptide is 17 amino acids comprised of the sequence "YAIRGV**DLNRV**SLLVD" bearing 21.5% identity to SEQ ID NO:2 residues 91-113 "HARLCLANFCGR**NRV**SLMCPSWS". In particular, the sequence bears 100% similarity where bolded and accordingly is a homolog of HARL in that it comprises the HARL motif with the H deleted and the RL substituted attached to additional sequences of the neural thread protein (NRVSL) as noted above. The claim does not require that the amino acids bear any particular homology to any particular portion of the neural thread protein sequence but merely require that they may be found in the full length sequence. In particular, the sequence bears 100% similarity where bolded and accordingly is a homolog of HARL attached to additional amino acids found in the neural thread protein. Further, while the reference is silent as to the peptide binding NTP such is deemed an inherent characteristic as the peptide is part of NTP and NTP is known and evidenced to bind to itself. Thus, this property is deemed inherent absent convincing factual evidence to the contrary. The PTO has insufficient resources to test for the property itself. Thus, the peptide meets the limitations of claims 56 directed to homologs and the mimetic of claims 57 and 58. (The mimetics themselves are not limited either structurally or functionally and thus any peptide bearing any region of similarity to the peptide would meet the limitations of a mimetic.)

18. Claims 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by de la Monte et al., US Patent 5,830,670 filed 5-30-1995 and issued 11-3-1998.

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Claims 57-58 are drawn to "An isolated mimetic". The limitations of "said peptide" are not limitations of the mimetic. de la Monte et al., teach isolated neural thread protein comprising or having the HARL motif, see in particular SEQ ID NO:120. The peptide is flanked by portions of the neural thread protein sequence. Moreover, Monte notes that neural thread protein aggregates and binds to itself, see in particular examples 2-3, 12 and 14-16, particularly in Alzheimer's and Down's syndrome plaques. Thus, as the mimetic is not delimited via any structural or functional limitations, the full length peptide would meet the claim limitations of a mimetic as the full length peptide approximates the peptide characteristics even though it is longer in length. Thus the reference teachings anticipate the claimed invention.

#### **Status of Claims**

19. No claims are allowed.

#### **Conclusion**

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.



Sharon L. Turner, Ph.D.

December 28, 2004

**SHARON L. TURNER, PH.D.**  
**PATENT EXAMINER**